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IN THE SPECIFICATION:

Insert the following new paragraph into the specification at page 1, line 1 immediately after the Title:

-- This application claims priority under 35 USC § 119 to US Provisional Application Serial No. 60/224,037, filed on August 9, 2000, and the Danish application DK PA 2000 01184, also filed on August 9, 2000. Each of these priority applications is incorporated herein, by reference in its entirety. --

IN THE CLAIMS:

Cancel claims 48-50 without prejudice or admission.

Amend claims 4-9, 11-14, 16-20, 24-29, 31-33, 35-39, 43-47 and 51-60, as indicated on the accompanying Exhibit A, and add new claims 62-64 so that the pending claims are as follows:

1. A parenteral vaccine formulation comprising at least one immunogenic substance, and as an adjuvant one or more salts selected from salts formed with a Group 2 element of the Periodic Table selected from Mg, Ca, Sr, Ba and Ra, or a Group 4 element of the Periodic Table selected from Ti, Zr, Hf, and Rf, and hydrates thereof, with the proviso that the salt is not calcium phosphate, is not magnesium hydroxide in combination with aluminium hydroxide or aluminium oxide

and is not calcium hydroxide in gel combination with zinc hydroxide, lecithin and polyalphaolefine.

2. A parenteral vaccine formulation according to claim 1, wherein the adjuvant is selected from inorganic salts.

3. A parenteral vaccine formulation according to claim 1, wherein the adjuvant is selected from organic salts.

4. (Amended) A parenteral vaccine formulation according to claim 1, wherein the adjuvant is selected from salts formed with oxides, peroxides, hydroxides, carbonates, phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

5. (Amended) A parenteral vaccine formulation according to claim 1, wherein the adjuvant is selected from salts formed between Mg, Ca, Ba, Ti, or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

6. (Amended) A parenteral vaccine formulation according to claim 1, wherein the adjuvant is selected from salts formed between magnesium and oxide,

peroxide, hydroxide, and/or carbonate, calcium and oxide, peroxide, hydroxide, and/or carbonate, barium and oxide, peroxide, hydroxide, and/or carbonate, titanium and oxide, peroxide, hydroxide, and/or carbonate, and zirconium and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

7. (Amended) A parenteral vaccine formulation according to claim 1, wherein the adjuvant is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, beryllium oxide, calcium sulphate, calcium silicate, dicalcium silicate, tricalcium silicate, calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium oxide, magnesium dioxide, magnesium sulphate, trimagnesium phosphate, magnesium silicate, dimagnesium trisilicate, magnesium trisilicate, titantium disulphate, zirconium dioxide, zirconium hydroxide, zirconium sulphate, strontium peroxide, and strontium carbonate.

8. (Amended) A parenteral vaccine formulation according to claim 1, wherein the adjuvant is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

9. (Amended) A parenteral vaccine formulation according to claim 1 further comprising an additional adjuvant.

10. A parenteral vaccine formulation according to claim 9, wherein the additional adjuvant is selected from saponins such as Quil A and Qs-21, MF59, MPL, PLG, PLGA, calcium phosphate, and aluminium salts.

11. (Amended) A parenteral vaccine formulation according to claim 1, further comprising pharmaceutically acceptable excipients and/or carriers.

12. (Amended) A parenteral vaccine formulation according to claim 1, further comprising diluents, buffers, suspending agents, solubilising agents, pH-adjusting agents, dispersing agents, and/or colorants.

13. (Amended) A parenteral vaccine formulation according to claim1, for intravenous, intramuscular, intraarticular, subcutaneous, intradermal, epicutantous, and intraperitoneal administration.

14. (Amended) A parenteral vaccine formulation according to claim1, wherein the cation of the adjuvant is present in an amount of from about 0.0004 to about 120 M, such as from about 0.004 to about 12 M.

15. A parenteral vaccine formulation according to claim 1, wherein the cation of the adjuvant is present in an amount of from about 0.008 to about 6 M.

16. (Amended) A parenteral vaccine formulation according to claim1, wherein the adjuvant is magnesium hydroxide.

17. (Amended) A parenteral vaccine formulation according to claim 1, wherein the adjuvant is magnesium carbonate hydroxide pentahydrate.

18. (Amended) A parenteral vaccine formulation according to claim1, wherein the adjuvant is titanium dioxide.

19. (Amended) A parenteral vaccine formulation according to claim1, wherein the adjuvant is a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

20. (Amended) A parenteral vaccine formulation according to claim16 further comprising an additional adjuvant selected from saponins such as Quil A and Qs-21, MF59, MPL, PLG, PLGA, calcium phosphate, and aluminium salts.

21. An adjuvant composition for parenteral use comprising one or more salts selected from salts formed with a Group 2 element of the Periodic Table selected from Mg, Ca, Sr, Ba and Ra, or a Group 4 element of the Periodic Table selected from Ti, Zr, Hf, and Rf,

and hydrates thereof,

with the proviso that the salt is not calcium phosphate, is not magnesium hydroxide in combination with aluminium hydroxide or aluminium oxide and is not calcium hydroxide in gel combination with zinc hydroxide, lecithin and polyalphaolefine.

22. An adjuvant composition according to claim 21, wherein the salt is selected from inorganic salts.

23. An adjuvant composition according to claim 21, wherein the salt is selected from organic salts.

24. (Amended) An adjuvant composition according to claims 21 wherein the salt is selected from salts formed with oxides, peroxides, hydroxides, carbonates, phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

25. (Amended) An adjuvant composition according to claim 21, wherein the salt is selected from salts formed between Mg, Ca, Ba, Ti or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

26. (Amended) An adjuvant composition according to claim 21, wherein the salt is selected from salts formed between magnesium and oxide, peroxide, hydroxide, and/or carbonate, calcium and oxide, peroxide, hydroxide, and/or carbonate, barium and oxide, peroxide, hydroxide, and/or carbonate, titanium and oxide, peroxide, hydroxide, and/or carbonate, and zirconium and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

27. (Amended) An adjuvant composition according to claim 21, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, beryllium oxide, calcium sulphate, calcium silicate, dicalcium silicate, tricalcium silicate, calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium oxide, magnesium dioxide, magnesium sulphate, trimagnesium phosphate, magnesium silicate, dimagnesium trisilicate, magnesium

trisilicate, titantium disulphate, zirconium dioxide, zirconium hydroxide, zirconium sulphate, strontium peroxide, and strontium carbonate.

28. (Amended) An adjuvant composition according to claim 21, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

29. (Amended) An adjuvant composition according to claim 21 further comprising an additional adjuvant.

30. An adjuvant composition according to claim 29, wherein the additional adjuvant is selected from saponins such as Quil A and Qs-21, MF59, MPL, PLG, PLGA, calcium phosphate, and aluminium salts.

31. (Amended) An adjuvant composition according to claim 21 further comprising pharmaceutically acceptable excipients and/or carriers.

32. (Amended) An adjuvant composition according to claim 21 further comprising diluents, buffers, suspending agents, solubilising agents, pH-adjusting agents, dispersing agents, and/or colorants.

33. (Amended) An adjuvant composition according to claim 21, wherein the cation of the salt is present in an amount of from about 0.0004 to about 120 M, such as from about 0.004 to about 12 M.

34. An adjuvant composition according to claim 33, wherein the cation of the salt is present in an amount of from about 0.008 to about 6 M.

35. (Amended) An adjuvant composition according to claim 21, wherein the salt is magnesium hydroxide.

36. (Amended) An adjuvant composition according to claim 21, wherein the salt is magnesium carbonate hydroxide pentahydrate.

37. (Amended) An adjuvant composition according to claim 21, wherein the salt is titanium dioxide.

38. (Amended) An adjuvant composition according to claim 21, wherein the salt is a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

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39. (Amended) An adjuvant composition according to claim 35 further comprising an additional adjuvant selected from saponins such as Quil A and Qs-21, MF59, MPL, PLG, PLGA, calcium phosphate, and aluminium salts.

40. An adjuvant comprising one or more salts selected from salts formed with a Group 2 element of the Periodic Table selected from Mg, Ca, Sr, Ba and Ra, or a Group 4 element of the Periodic Table selected from Ti, Zr, Hf, and Rf, and hydrates thereof,
with the proviso that the salt is not calcium phosphate, is not magnesium hydroxide in combination with aluminium hydroxide or aluminium oxide and is not calcium hydroxide in gel combination with zinc hydroxide, lecithin and polyalphaolefine.

41. An adjuvant according to claim 40, wherein the salt is selected from inorganic salts.

42. An adjuvant according to claims 40, wherein the salt is selected from organic salts.

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43. (Amended) An adjuvant according to claim 40, wherein the salt is selected from salts formed with oxides, peroxides, hydroxides, carbonates,

phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

44. (Amended) An adjuvant according to claim 40, wherein the salt is selected from salts formed between Mg, Ca, Ba, Ti or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

45. (Amended) An adjuvant according to claim 40 wherein the salt is selected from salts formed between magnesium and oxide, peroxide, hydroxide, and/or carbonate, calcium and oxide, peroxide, hydroxide, and/or carbonate, barium and oxide, peroxide, hydroxide, and/or carbonate, titanium and oxide, peroxide, hydroxide, and/or carbonate, and zirconium and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

46. (Amended) An adjuvant according to claim 40 wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, calcium sulphate, tricalcium silicate, calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium sulphate, trimagnesium phosphate,

magnesium silicate, magnesium trisilicate, titantium disulphate, zirconium sulphate, strontium peroxide, and strontium carbonate.

47. (Amended) An adjuvant according to claim 40, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide, or the salt is selected from a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

51. (Amended) A method according to claim 64, wherein the salt is selected from inorganic salts.

52. (Amended) A method according to claim 64, wherein the salt is selected from organic salts.

53. (Amended) A method according to claim 64, wherein the salt is selected from salts formed with oxides, peroxides, hydroxides, carbonates, phosphates, pyrophosphates, hydrogenphosphates, dihydrogenphosphates, sulphates, and/or silicates, and hydrates thereof.

54. (Amended) A method according to claim 64 wherein the salt is selected from salts formed between Mg, Ca, Ba, Ti, or Zr, and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

55. (Amended) A method according to claim 64, wherein the salt is selected from salts formed between magnesium and oxide, peroxide, hydroxide, and/or carbonate, calcium and oxide, peroxide, hydroxide, and/or carbonate, barium and oxide, peroxide, hydroxide, and/or carbonate, titanium and oxide, peroxide, hydroxide, and/or carbonate, and zirconium and oxide, peroxide, hydroxide, and/or carbonate, and hydrates thereof.

56. (Amended) A method according to claim 64, wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, titanium dioxide, calcium carbonate, barium hydroxide, barium peroxide, barium carbonate, barium sulphate, beryllium oxide, calcium sulphate, calcium silicate, dicalcium silicate, tricalcium silicate, calcium pyrophosphate, calcium peroxide, calcium hydroxide, tricalcium phosphate, calcium hydrogenphosphate, calcium dihydrogenphosphate, calcium sulphate dihydrate, magnesium carbonate, magnesium oxide, magnesium dioxide, magnesium sulphate, trimagnesium phosphate, magnesium silicate, dimagnesium trisilicate, magnesium

trisilicate, titantium disulphate, zirconium dioxide, zirconium hydroxide, zirconium sulphate, strontium peroxide, and strontium carbonate.

57. (Amended) A method according to claim 64 wherein the salt is selected from magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide, or wherein the salt is selected from a combination of magnesium hydroxide and magnesium carbonate hydroxide pentahydrate, magnesium hydroxide and titanium dioxide, magnesium carbonate hydroxide pentahydrate and titanium dioxide, or magnesium hydroxide, magnesium carbonate hydroxide pentahydrate, and titanium dioxide.

58. (Amended) A method of generating an immune response in a subject comprising administering to the subject a parenteral vaccine formulation according to claim 1.

59. (Amended) A method for vaccination or treatment of a vertebrate including a human being comprising administering a vaccine formulation according to claim 1.

60. (Amended) A process for preparing a parenteral vaccine formulation according to claim1 comprising adding liquid to a dry form of or a pre-formed gel of

the salt formed with a Group 2 element of the Periodic Table selected from Mg, Ca, Sr, Ba and Ra, or a Group 4 element of the Periodic Table selected from Ti, Zr, Hf, and Rf, the salt not being calcium phosphate, not being magnesium hydroxide in combination with aluminium hydroxide or aluminium oxide and not being calcium hydroxide in gel combination with zinc hydroxide, lecithin and polyalphaolefine, thereby obtaining an adjuvant composition, and mixing said adjuvant composition with one or more immunogenic substances and optionally pharmaceutically acceptable carriers and/or excipients, thereby obtaining the parenteral vaccine formulation.

61. A parenteral vaccine formulation obtainable by the process according to claim 60.

62. (New) A method for preparing a parenteral vaccine formulation, which method comprises combining:

(a) an adjuvant composition according to claim 39;

(b) at least on immunogenic substance; and optionally

(c) one or more pharmaceutically acceptable carriers and/or excipients,

so that a parenteral vaccine formulation is obtained.

63. (New) A method for preparing a parenteral vaccine formulation, which method comprises combining:

(a) an adjuvant composition according to claim 40;

(b) at least on immunogenic substance; and optionally

(c) one or more pharmaceutically acceptable carriers and/or excipients,

so that a parenteral vaccine formulation is obtained.

64. (New) A method for preparing a vaccine formulation for parenteral admission, which method comprises combining:

(a) as an adjuvant, a salt formed with a Group 2 element of the Periodic Table selected from Mg, Ca, Sr, Ba and Ra, or a Group 4 element of the Periodic Table selected from Ti, Zr, Hf and Rf, and hydrates thereof, with the proviso that the salt is not calcium phosphate, is not magnesium hydroxide in combination with aluminium hydroxide or aluminium oxide and is not calcium hydroxide in gel combination with zinc hydroxide, lecithin and polyalphaolefine;

(b) at least on immunogenic substance; and optionally

(c) one or more pharmaceutically acceptable carriers and/or excipients,

so that a vaccine formulation suitable for parenteral admission is obtained.